

The following are highlights of the changes made to the Quality Systems section (Chapter 5) of the 2002 NELAC Standards (effective as of July 1, 2004).

#### Major Points of NELAC 2002 Standards

- Incorporation of ISO 17025 Standards with new formatting.
- Sections divided into management and technical requirements.
- Focus on the client.
- Incorporation of ISO 9000:1994.
- Client services are in line with PBMS applications.
- Requirement for determination of uncertainty.
- **Management**
- Big change in document control.
  - Lab must now control not only internal but *external* documentation.
  - Changes must be authorized and signed by person who approved *original* SOP.
- New contract review requirements.
  - Now expanded not only to formal contracts but to requests and tenders.
  - Lab must give client opportunity to view services performed without compromising confidentiality.
  - Lab is now required to tell client if method is not appropriate for their use.
  - Lab must filter down to the *analyst* any modification or changes to the contract.
- New wording for purchasing.
  - Lab is now required to *evaluate* suppliers and document it.
- Expanded corrective actions section.
  - Lab is now required to document policies and procedures for the resolution of complaints from clients and *other parties*.
  - Lab is required to perform root cause analysis of the problem.
  - Lab must determine best corrective action to solve the problem and *prevent* its recurrence.
  - “Immediate” corrective action is now defined by the lab.
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- New section on non-conforming work (work that does not conform to lab’s own procedures or client’s agreed requirements).
- Records divided between administrative and technical functions.
- Require more management participation in quality programs with documentation.
  - Define management’s involvement or influence in *potential* conflicts of interest.
  - Lab must provide *annual* refresher training for data integrity (ethics).
  - Lab must provide training *goals* for technical staff.

- **Technical**
- Method validation is defined and required for non-standard methods.
  - All method validation procedures are to be performed.
- Labs are required to estimate uncertainty of measurements.
  - Minimally, to try and identify and make reasonable estimations (can use control charts, etc.)
  - Use of standard test methods satisfies the requirement.
- Lab equipment (including software) must meet accuracy and method specification requirements.
- Single point calibration standard must meet established acceptance criteria (LCS).
- Lab must have sampling plans and procedures including aliquots.
- Test reporting has been expanded.
  - Must meet the needs of the client.
  - Uncertainty must be reported for radiochemistry and WET.
  - All elements must be available even if not reported.
  - Opinions and interpretations must also be included.